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09/403,085	01/07/2000	ABDELHAMID ELAISSARI	104560	6821

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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/403,085	ELAISSARI ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-29 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-3,6-29 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims Under Prosecution

1. Applicant's request for entry and consideration of claims 1-32, filed 3/25/02, is acknowledged. Due to inadvertent exclusion of claims 26-32 and inadvertent non-entry of amendment to claims 1-25 by the Office, a second non-final Office Action is being issued to Applicant. The Office regrets any inconveniences brought upon Applicant by this oversight.

Amendment Entry

2. Applicant's amendment and response file 3/25/02 is acknowledged and has been entered. Claims 4, 5, and 30-32 have been cancelled. Claims 1-3 and 6-29 have been amended. Claim 33 has been added. Accordingly, claims 1-3, 6-29, and 33 are pending and are currently under examination.

Rejections Withdrawn

3. In light of Applicant's amendment and argument, the rejection of claims 1-3, 8-15, 17, and 19-26 under 35 U.S.C. 102(b) as being anticipated by Rohr et al. (US 5,445,971) is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 6-29, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting, "these groups being covalently bound to said first hydrophilic polymer and coordinated by a first transition metal" because it is unclear what Applicant intends to encompass in using the term "coordinated". Does Applicant intend that the first transition metal takes part in the covalent binding between the first hydrophilic polymer and the first complexing groups? Please clarify.

Claim 2 is vague and indefinite in reciting, "the capture phase comprises a marker for use as a detection phase" because it is unclear as recited as to whether the detection phase is a further embodiment of the capture phase, or a separate element from the capture phase that plays a role in the process for isolating a target biological material. Subsequent claims appear to recite the detection phase as a separate element. If so, it appears that claim 2 should recite, "wherein the process (in claim 1) further comprises contacting the complex with a detection phase for detecting ...".

Claim 3 is vague and indefinite in reciting, "second complexing groups which are coordinated to a second transition metal" because it is unclear what Applicant intends to encompass in using the term "coordinated". Does Applicant intend that the second complexing groups relate by way of binding, to the second transition metal? Please clarify.

Claim 3 is confusing because it is unclear what structural and functional cooperative relationship exists between each and all of the second hydrophilic polymer, second complexing groups, second transition metal, and second biological species, and the marker which appears to be a label, as recited in subsequent claim 28. It is further unclear what structural and functional cooperative relationship exists between each and all of the second hydrophilic polymer, second complexing groups, second transition metal, and second biological species of the detection phase and each and all of the first hydrophilic polymer, first complexing groups, first transition metal, and first biological species of the capture phase.

Claim 23 is vague and indefinite in lacking antecedent basis for the recitation of "contacting of the first biological species with the capture phase" because the first biological species appears to be one of the elements that the capture phase consists of. Additionally, claim 1 from which claim 23 depends, recites, "contacting the biological target material with at least a capture phase".

Claim 24 is vague and indefinite in lacking antecedent basis for the recitation of "contacting of the first biological species with the detection phase" because the first biological species appears to be one of the elements that the detection phase consists of. Additionally, all of claims 1-3 from which claim 24 depends, recite, "contacting the biological target material with at least a capture phase" and "the capture phase comprises ... the detection phase".

Claim 27 is vague and indefinite in reciting, "agglutination reaction is used" because it is unclear how agglutination reaction is used so as to functionally relate to

the elements recited in claim 1 in a process for isolating a biological material contained in a sample.

Claim 28 is vague and indefinite in reciting, "the marker ... comprises a material selected from the group consisting of ... an antigen, a hapten, and an antibody" because it is unclear how antigens, haptens, and antibodies are used as markers, i.e. label.

Claim 29 is vague and indefinite in reciting, "ELISA is used" because it is unclear how ELISA is used so as to functionally relate to the elements recited in claims 1 and 2 in a process for isolating a biological material contained in a sample.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 1-3, 6, 7, 11, 12-15, and 17, 18, and 21-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nowinski et al. (US 4,843,010) for reason of record.

Nowinski et al. disclose a process of isolating (separating) a target biological material (analyte) in a sample by contacting the target with a capture phase to form a

complex. The capture phase comprises a monomer-biological species conjugate (monomer-reactant conjugate) wherein the biological species is an antigen or antibody that specifically recognizes the target. Specifically, the biological species is covalently linked with a functionalized polymer obtained by polymerization of a water-soluble monomer such as acrylamide or methacrylamide (see column 2, lines 40-62 and column 1, lines 50-59). The monomer is typically an ethylenically or acetylenically unsaturated compound containing a functionality for coupling to the biological species; such functionalities include covalently bondable functionalities such as carboxyl, amine, etc. (see column 6, lines 55-67). The monomer, biological species, and its specific target bind through interaction to form a complex by initiating polymerization reaction; thereby rapidly and conveniently separating the complex or isolating the target from the solution (see column 3, lines 40-53). The isolation of bound from free biological species is effected by polymerization reaction (see column 4, lines 45-47). Nowinski teach that the biological species includes a marker or detection phase (reporter) which is capable of producing a detectable signal, either alone or in combination with the capture phase, such as radioisotopes, fluorophores, chromophores, and luminescent compounds (see column 5, lines 3-8). In addition, the complexing groups may further be linked to or include photoinitiators for photoinitiated polymerization using transition metals such as iron or cobalt (see column 9, lines 58-65). The solid phase supports taught by Nowinski et al. (insoluble polymer particles) comprise cores which are cross-linked for immobilization of biological species; these include polystyrene and polyacrylamides (see column 2, lines 15-19). In column 5, Nowinski et al. disclose that the isolation or

separation procedure encompass agglutination reactions and ELISA techniques. The pH range used in the process varies widely from pH 3 to pH 10 although it is preferable to select a pH wherein the biological species remains stable, i.e. above or equal to the isoelectric point of the species (see column 9, lines 21-37). According to Nowinski et al., by varying the chemical composition or ratios of monomers, it is possible to form either hydrophilic (soluble) or hydrophobic (insoluble) polymers which comprise a broad range of chemical and physical structures including linear, branched, or cross-linked structures (see column 2).

6. Claims 1-3, 6, 7, 9, 10-12, 15-18, 21, 23-26, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Owen et al. (US 5,866,099).

Owen et al. disclose magnetic polymer particles for use as capture phase in immunoassays (see Abstract). The magnetic polymer particles consist of hydrophilic polyacrylic polymers or polyacrylamine. The particles are magnetic due to coordination of magnetic metal compounds such as iron and magnetite into polyacrylamine or polyacrylic polymers. The polymer particles have a size that is about 0.01 – 0.2 microns (see columns 3 and 4 and Example 1A). The polymer particles have complexing groups (cross-linking agents) covalently bound thereto, and can be tailored to include monomers which exhibit biofunctional activities, such as by including antibodies (Example 2) and a marker (radioisotope) for use as a tracer of protein component (Example 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 8 and 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nowinski et al. (US 4,843,010) or Owen et al. (US 5,866,099) in view of Schaeffer et al. (US 4,784,912).

Nowinski et al. or Owen have been discussed supra. Nowinski et al. or Owen et al. differ from the instant invention in failing to disclose N-isopropylacrylamide as the water-soluble monomer incorporated into the capture phase or polymer particles.

Schaeffer et al. disclose polymeric latex particles which have incorporated thereto recurring units of hydrophilic or water soluble polymerizable monomers including acrylamide, methacrylamide, and N-isopropylacrylamide (see column 5).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute N-isopropylacrylamide such as taught by Schaeffer for the acrylamide or methacrylamide on the solid phase particle taught by Nowinski or Owen because Nowinski and Owen specifically are generic with the type of hydrophilic polymerizable monomers used and Schaeffer specifically taught that N-isopropylacrylamide, constitutes an obvious variation of acrylamides or methacrylamides which are routinely varied in the art.

8. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nowinski et al. (US 4,843,010) or Owen et al. (US 5,866,099) in view of Schaeffer et al. (US 4,784,912) and in further view of Ohdaira et al. (US 5,132,243).

Nowinski et al., Owen et al., and Schaeffer et al. have been discussed supra. Nowinski et al., Owen et al., and Schaeffer et al. differ from the instant invention in failing to teach that the complexing groups are derived specifically from itaconic acid or maleic anhydride-co-methyl vinyl ether.

Ohdaira et al. disclose polymeric latex particles which have incorporated thereto a copolymer of ethylene and an α,β-ethylenically unsaturated carboxylic acid and further

having an aromatic vinyl compound grafted thereto. The α,β-ethylenically unsaturated carboxylic acid is at least one of itaconic acid and maleic acid (see column 2). Further, the polymer particle can be sensitized or chemically bonded with an immuno-serologically active material such as antigen or antibody (see column 4).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute itaconic acid or maleic acid such as taught by Ohdaira for the complexing groups in the polymer particles taught by Nowinski or Owen because both Nowinski and Owen are generic with the type of complexing agents used and itaconic acid or maleic acid constitutes obvious variations of complexing groups used to facilitate attachment of biological species into polymer particles which are routinely varied in the art.

Response to Arguments

9. Applicant's arguments filed 3/25/02 have been fully considered but they are not persuasive.

A) Applicant argues that claims 1-3, 6-8, 10-12, 14-15, and 17-29 are not anticipated by Nowinski because the transition metals in the Nowinski reference serve to initiate polymerization of the monomer and will, at most, be present only at the ends of the resulting polymer. Applicant contends that the transition metal in the claimed invention forms a coordinate covalent bond with the complex group attached to the hydrophilic polymer; hence is a constitutive element of the capture phase. Applicant

further argues that the transition metal in Nowinski does not interact with, nor is it bound to, the reactant portion of the detection phase.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant rely (i.e., 1) transition metal forms a coordinate covalent bond with the complex group attached to the hydrophilic polymer, and 2) the transition metal interacts with and is bound to, the reactant portion of the detection phase) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, claim 1 only recites that the capture phase consists of a hydrophilic polymer and complexing groups, wherein the complexing groups are covalently bound to the hydrophilic polymer, and coordinated by a transition metal. Accordingly, the teaching of Nowinski reads on the claim 1.

B) Applicant argues that the Owen reference does not anticipate the claimed invention because while the polymer as taught by Owen et al. is associated to the metal via coordination, the metal is not directly linked to the biological material. Applicant specifically contends that in the Owen reference, the transition metal does not interact with the biological material.

In response to Applicant's argument that the reference fails to teach certain elements of the claimed invention, it is noted that the features upon which Applicant rely, i.e. 1) the transition metal is directly linked to the biological material, and 2) the

transition metal interacts with the biological material, are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, claim 1 recites only that, "the transition metal is chelated to a biological species having specific affinity to the biological material". Accordingly, the teaching of Owen et al. appears to read on the claimed invention.

C) Applicant argues that the combination of Nowinski or Owen with Schaeffer fails to teach or suggest the use of N-isopropyl acrylamide as the water-soluble monomer that is incorporated into the capture phase or polymer particles. Applicant specifically contends that the combination of Nowinski or Owen with Schaeffer would only yield the linkage of transition metal to the polymer particles, but still fails to cure the deficiencies of Nowinski or Owen because the combined teachings of the references fails to teach or suggest the direct linkage of the transition metal to the biological material.

In response to Applicant's argument that the combined references fail suggest certain elements of the claimed invention, it is noted that the features upon which Applicant rely, i.e. the transition metal is directly linked to the biological material, hence, interacts with the biological material, is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed.

Cir. 1993). In this case, claim 1 recites only that, "the transition metal is chelated to a biological species having specific affinity to the biological material". Accordingly, the combined teaching of Nowinski or Owen with Schaeffer appears to suggest the claimed invention.

D) Applicant argues that the combination of Nowinski or Owen with Schaeffer in further view of Ohdaira fails to teach or suggest that the complexing groups or functional monomers are derived from itaconic acid or from maleic anhydride-co-methyl vinyl ether. Applicant specifically contends that although suggestive that the polymer particle can be chemically bonded to antigen or antibody, the combination of Nowinski or Owen with Schaeffer in further view of Ohdaira still would not suggest direct linkage of the transition metal to the biological material to cure the deficiencies of Nowinski or Owen.

In response to Applicant's argument that the combined references fail suggest certain elements of the claimed invention, it is noted that the features upon which Applicant rely, i.e. direct linkage of the transition metal to the biological material, is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, claim 1 recites only that, "the transition metal is chelated to a biological species having specific affinity to the biological material". Accordingly, the combined teaching of Nowinski or Owen with Schaeffer and in further view of Ohdaira appears to suggest the claimed invention.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
March 1, 2005

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3/2/05